

David Bliesner, Ph.D.

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1 Q. When you have worked as a consultant for 03:17  
2 Quantic Regulatory Services, have you done batch 03:17  
3 record reviews for them or for other companies and 03:17  
4 other products? 03:17

5 A. No. And if I could, please, when you 03:17  
6 say Quantic Regulatory Services, there's -- if I'm 03:17  
7 not mistaken there's like three entities of 03:17  
8 Quantic. One is the regulatory services, one 03:17  
9 Quantic, and there's another one, depending on 03:17  
10 what the job is covered by. 03:17

11 So to answer that question accurately, I'm not 03:17  
12 sure which one we're referring to, which one of 03:17  
13 those business entities, just to be clear. 03:17

14 Q. How many companies -- how many other 03:18  
15 companies that you worked for in the 03:18  
16 pharmaceutical industry were at one point on 03:18  
17 consent decree? 03:18

18 A. As a permanent employee worked for? 03:18

19 Q. Yeah. 03:18

20 A. At one point? 03:18

21 Q. Yeah. 03:18

22 A. To my knowledge, none of the companies. 03:18

23 Q. What about in your consulting 03:18  
24 arrangements? How many of the companies have been 03:18  
25 on consent decree at some point? 03:18

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1 A. That I know of? 03:18

2 Q. Yeah. 03:18

3 A. Two. 03:18

4 Q. And Wyeth was one. Are you able to tell 03:18

5 me who the other one is? 03:18

6 A. Schering Plough. 03:18

7 Q. When you were working with those 03:18

8 companies regarding consent decrees, did you tell 03:18

9 them that a consent decree was because of a 03:19

10 repeated and persistent non-compliance with the 03:19

11 law? 03:19

12 A. That was not my function to tell the 03:19

13 companies that. So me personally, no. 03:19

14 Q. Did you believe when you were consulting 03:19

15 with them that they were on consent decree because 03:19

16 of repeated, persistent non-compliance with the 03:19

17 law? 03:19

18 MR. KERENSKY: Wait a minute. I want to 03:19

19 caution you there. 03:19

20 THE WITNESS: Yeah. 03:19

21 MR. KERENSKY: We're on the same page. 03:19

22 Because you're now asking him to say 03:19

23 something, a conclusion he drew based on stuff 03:19

24 he knew about while working there and working 03:19

25 with them, which may be covered by the 03:19

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1 confidentiality agreements he has. 03:19

2 THE WITNESS: All I know, if I could, is 03:19

3 that these companies all post the consent 03:19

4 decree and the letter by quality assurance and 03:19

5 management on bulletin boards so everybody can 03:20

6 see what it's all about. That's part of the 03:20

7 function. 03:20

8 BY MR. MORIARTY: 03:20

9 Q. I understand that. But do you -- I mean 03:20

10 you have said that my client or pharmaceutical 03:20

11 companies in general go on consent decree for 03:20

12 repeated, persistent non-compliance with the law, 03:20

13 and I'm trying to find out whether that is a 03:20

14 phrase that you're applying only to Actavis or 03:20

15 whether you also apply it to companies that you 03:20

16 consult with in the non-litigation world. 03:20

17 A. Again, I'm not -- 03:20

18 THE VIDEOGRAPHER: Five minutes. 03:20

19 THE WITNESS: Again, I'm not sure I 03:20

20 really understand the gist of the question. I 03:20

21 apologize. 03:20

22 BY MR. MORIARTY: 03:21

23 Q. Okay. At page 8 of your report. 03:21

24 A. Okay. 03:21

25 Q. It says: 03:21

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1 "It should be noted in my experience consent 03:21  
2 decrees are not common and mostly occur when a 03:21  
3 company has shown repeated and persistent 03:21  
4 non-compliance with the law." 03:21

5 Do you see that? 03:21

6 A. Yes, I do. 03:21

7 Q. All right. What I'm trying to find out 03:21  
8 about, Dr. Bliesner, is whether you are just 03:21  
9 making a comment about my client or whether that 03:21  
10 is your opinion about pharmaceutical companies and 03:21  
11 the consent decree generally. 03:21

12 A. Yes. 03:21

13 Q. Yes which? 03:21

14 A. They -- that it takes an awful lot to 03:21  
15 get a consent decree. It's a progress of numerous 03:21  
16 483s, warning letters in most circumstances. 03:21  
17 Sometimes they go directly to it. There's 03:21  
18 numerous 483s, warning letters, and then it gets 03:21  
19 to the point where the agency says we don't have 03:21  
20 enough resources anymore to manage this. Let's go 03:21  
21 into an agreement. 03:22

22 Q. And have you ever consulted with a 03:22  
23 pharmaceutical company about a product that was in 03:22  
24 litigation, product liability litigation? 03:22

25 A. Consulted specifically about the product 03:22



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1 liability? 03:22

2 Q. Yeah. 03:22

3 A. No. 03:22

4 Q. Does the ANDA for any product, including 03:22

5 Digitek, contain the formula for the active 03:22

6 ingredients and how they are to be blended? 03:22

7 A. The formula, yeah. The combination of 03:22

8 excipients and active. 03:22

9 Q. Yes. 03:22

10 A. In my experience they do contain that. 03:22

11 Q. And presumably they have to be mixed in 03:22

12 appropriate proportions in order to comply with 03:22

13 the formula; correct? 03:22

14 A. They need to follow their manufacturing 03:23

15 steps in order to -- to come up with a proper 03:23

16 dosage for them, whether it involved mixing or 03:23

17 whatever. 03:23

18 Q. And those steps are approved by the FDA; 03:23

19 correct? 03:23

20 A. Those steps are in the application. If 03:23

21 the application is approved and the FDA has found 03:23

22 the information in the application acceptable. 03:23

23 THE VIDEOGRAPHER: We should definitely 03:23

24 change tapes. 03:23

25 The time is 3:26 p.m. We're going off 03:23

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1 the record. 03:23

2 THE VIDEOGRAPHER: The time is now 03:34

3 3:37 p.m. We are back on the record. This is 03:34

4 the beginning of tape six. 03:34

5 BY MR. MORIARTY: 03:34

6 Q. Okay. We were asking before the break 03:34

7 about formulas; okay? Have you seen any 483 or a 03:34

8 warning letter, any sort of citation or sanction 03:35

9 by the FDA on Actavis for any problem with the 03:35

10 actual mixing of the ingredients? In other words, 03:35

11 using inappropriate proportions of ingredients? 03:35

12 A. Proportions? 03:35

13 Q. Yes. 03:35

14 A. Not that I recall. 03:35

15 Q. So you don't have any evidence that any 03:35

16 Digitek batch started with too much active 03:35

17 pharmaceutical raw ingredient? 03:35

18 A. I don't have any evidence. 03:35

19 Q. You are aware that Actavis tests every 03:36

20 batch at the blend stage. 03:36

21 A. Every batch at the blend stage? 03:36

22 Q. Yeah. 03:36

23 A. I don't have information that I've seen 03:36

24 that confirms or denies that. 03:36

25 Q. Okay. 03:36

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1 In your work in the pharmaceutical industry -- 03:36

2 not in your consulting work -- how much contact 03:36

3 did you have with blend uniformity sampling or 03:36

4 testing? 03:36

5 A. Testing. 03:36

6 Q. So not sampling? 03:36

7 A. No. 03:36

8 Q. Not the core sampling? 03:36

9 A. No. 03:36

10 Q. But you did have some with testing? 03:36

11 A. Yes. 03:36

12 Q. And typically when a company does blend 03:36

13 sampling from a dry blend batch, how many core 03:36

14 samples do they take and submit to a QC lab for 03:37

15 analysis? 03:37

16 A. That varies. It's not a set thing. 03:37

17 Q. From your reading -- 03:37

18 A. And it's always a battle. 03:37

19 Q. Why is it a battle? 03:37

20 A. Because the lab always wants less 03:37

21 samples and the validation people want more 03:37

22 samples, and they go back and forth to try to 03:37

23 determine number of samples to be sent to be 03:37

24 analyzed. It's a very big challenge. 03:37

25 Q. Why does the lab want less samples? 03:37

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1 A. Because usually you're doing their 03:37  
2 release testing on top of process validation, so 03:37  
3 it's doubling their workload. 03:37

4 Q. From your reading in pharmaceutical 03:37  
5 publications over time, have you found that blend 03:37  
6 uniformity sampling and testing in general is a 03:37  
7 controversial subject? 03:37

8 A. Controversial? 03:37

9 Q. Yes, sir. 03:37

10 A. I wouldn't use the word controversial. 03:38

11 Q. Have there been efforts by 03:38  
12 pharmaceutical companies to have the FDA eliminate 03:38  
13 the requirement of blend uniformity sampling 03:38  
14 because it's notoriously difficult to do and 03:38  
15 control well? 03:38

16 A. I know that Actavis in some of their 03:38  
17 documentation make reference to try to stop blend 03:38  
18 uniformity testing. 03:38

19 Q. Do you know about any other company? 03:38

20 A. Specifically that I've been involved 03:38  
21 with? 03:38

22 Q. Actually I mean generally. 03:38

23 A. Generally. 03:38

24 Q. Your general knowledge of the industry. 03:38

25 A. Blend uniformity as I said is always a 03:38

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1 challenge anyway, so... 03:38

2 Q. Okay. So can you point to me any 03:38

3 document where the FDA cited or warned the company 03:38

4 because an actual batch had out-of-specification 03:38

5 blend uniformity samples? 03:39

6 A. The FDA cited? 03:39

7 Q. Yeah, which then went on uncorrected or 03:39

8 the tests weren't repeated? 03:39

9 A. It would -- there are references to 03:39

10 blend -- if I'm not mistaken there are references 03:39

11 in 483s and/or potentially EIRs with respect to 03:39

12 blend if I recall. I'd have to go back and dig 03:39

13 through and look at it specifically. 03:39

14 Q. Yeah, but do you know whether that had 03:39

15 to do with the way they investigated and the 03:39

16 number of samples -- and the number of samples 03:39

17 they took or whether it was actual blend 03:39

18 uniformity failures that were not addressed? 03:39

19 A. As I said, I would have to go back and 03:39

20 look specifically as what those discussions were. 03:39

21 It's been a while. 03:40

22 Q. Is it important to your opinions in this 03:40

23 case? 03:40

24 A. I think so, yes. 03:40

25 Q. Is there a difference between an actual 03:40

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1 blend uniformity failure that might require batch 03:40

2 rejection and some technical need to either 03:40

3 investigate differently or the way you did your 03:40

4 backup testing? 03:40

5 A. I don't understand that question. 03:40

6 Q. All right. It wasn't a very good 03:40

7 question. You'll find that late in the day with 03:40

8 this stuff, you can mess up the questions. 03:40

9 A. This is hard work. 03:40

10 Q. All right. So let's just assume that a 03:40

11 company takes ten core samples from various 03:40

12 sections of the blender for the blend uniformity 03:40

13 sampling; okay? 03:40

14 A. Yes. 03:40

15 Q. Now, let's assume that one of the ten is 03:40

16 out of specification. 03:40

17 A. Yes. 03:41

18 Q. Okay. 03:41

19 A. Uh-huh. 03:41

20 Q. A company is entitled to retest either a 03:41

21 portion of that sample or take a new sample from 03:41

22 that part of the blender, aren't they? 03:41

23 A. Retest, resample. You have to be very 03:41

24 careful on how you're defining those terms. 03:41

25 Q. Well, let's go back. Let's assume that 03:41

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1 the core sampling device, the sample thief. 03:41

2 A. Yes. 03:41

3 Q. Let's just assume for the sake of 03:41

4 argument -- 03:41

5 A. Uh-huh. 03:41

6 Q. -- that it is the length and diameter of 03:41

7 my pen -- 03:41

8 A. Okay. 03:41

9 Q. -- that I'm holding in front of the 03:41

10 camera; okay? 03:41

11 A. Uh-huh. 03:41

12 Q. So you put that in and you fill it with 03:41

13 blend. Actually, I think the sampling techniques 03:41

14 require a lot less than the length and diameter of 03:41

15 my pen. But let's assume you have enough to test, 03:42

16 okay, and you have some left over; all right? 03:42

17 A. Yes. 03:42

18 Q. Is there any FDA reg -- GMP or 03:42

19 otherwise -- that if the first test on the sample 03:42

20 is out of spec, it says that you have to reject 03:42

21 the batch and that you cannot test the remaining 03:42

22 sample in this sample field? 03:42

23 A. Well, there's a whole process that gets 03:42

24 to that, the resampling stage. If you have a 03:42

25 failure of an analysis in the laboratory, it 03:42

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1 requires a laboratory investigation to determine 03:42

2 whether that result is valid or not. 03:42

3 Q. Okay. But the question is, is there a 03:42

4 FDA reg that prevents you from testing more of the 03:42

5 sample that you took? 03:42

6 A. Not to my knowledge. 03:42

7 Q. Is there an FDA reg that prevents you 03:42

8 from resampling from that part of the blender and 03:43

9 then testing that material? 03:43

10 A. Not to my knowledge. 03:43

11 Q. Is there any FDA reg -- including GMP 03:43

12 regs -- that require companies to reject a batch 03:43

13 based on one out of say ten blend uniformity 03:43

14 tests? 03:43

15 A. Regulations? 03:43

16 Q. Yeah. 03:43

17 A. Not to my knowledge. 03:43

18 Q. So if we were to look at the Actavis 03:43

19 batch records and find that, for example, that on 03:43

20 initial testing, one sample was out of spec, and 03:43

21 the company did an investigation and retested and 03:43

22 it was not out of spec on retesting, you're not 03:44

23 saying that Actavis had to reject that batch for 03:44

24 blend uniformity failure, are you? Just answer my 03:44

25 question. 03:44



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1 A. Yeah. Say it again, please. These are 03:44

2 very difficult issues. 03:44

3 Q. Sure. 03:44

4 A. Very difficult issues and they happened 03:44

5 frequently. 03:44

6 Q. All right. So if you go into the 03:44

7 records -- 03:44

8 A. Yes. 03:44

9 Q. -- you've had, all this paper, and you 03:44

10 find that there was a blend uniformity out of spec 03:44

11 result -- 03:44

12 A. Yes. 03:44

13 Q. -- for one out of ten samples for a 03:44

14 particular batch; okay? 03:44

15 A. Uh-huh. 03:44

16 Q. Are you with me so far? 03:44

17 A. I am. 03:44

18 Q. And they retested it and it was within 03:44

19 the specs and hence passed blend uniformity and 03:44

20 was sent on for packaging, is it your opinion that 03:44

21 that one out of spec result would have -- would 03:44

22 have required rejection of the batch? 03:45

23 A. Perhaps. If you have a failure like 03:45

24 this and you can't find a root cause for it and 03:45

25 your investigation doesn't lead to anything, then 03:45

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1 there are some very serious discussions that need 03:45  
2 to be made with respect to the disposition of that 03:45  
3 batch. 03:45

4 Q. All right. But that doesn't 03:45  
5 automatically require a batch -- 03:45

6 A. Automatically -- 03:45

7 Q. -- rejection. 03:45

8 A. Automatically, knee jerk, no. 03:45

9 Q. You're supposed to -- the regs require 03:45  
10 that you do an investigation; correct? 03:45

11 A. Specifically I'd have to go back and 03:45  
12 look at the GMPs to see where they say -- excuse 03:45  
13 me -- say exactly that you must reject. It is 03:45  
14 expected in the industry that manufacturing 03:45  
15 investigations are investigated very thoroughly to 03:45  
16 determine a root cause. 03:45

17 Q. Okay. And it could be a manufacturing 03:45  
18 investigation or a lab investigation under these 03:46  
19 circumstances we're talking about with blend 03:46  
20 uniformity, couldn't it? 03:46

21 A. Yes, the lab in most cases is involved 03:46  
22 even if it is a manufacturing investigation 03:46  
23 because the laboratory people have a tendency to 03:46  
24 be some of the more technically trained folks on 03:46  
25 the staff and they usually are cross-functional 03:46

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1 teams when these types of issues come up. So you 03:46  
2 can solve the problem with the best information we 03:46  
3 have. 03:46

4 Q. So if there is a circumstance in the 03:46  
5 documents where this has occurred, FDA could go 03:46  
6 back and say we don't like the way you conducted 03:46  
7 the investigation and write up an observation and 03:46  
8 a 483 just about the way the investigation was 03:46  
9 done; correct? 03:46

10 A. That is correct. 03:46

11 Q. But not necessarily go the next step and 03:46  
12 say you should have rejected the batch. 03:46

13 A. It could; it could not. 03:47

14 Q. Right. 03:47

15 A. Uh-huh. 03:47

16 Q. But it doesn't follow as night does day 03:47  
17 that they would say you have to reject the batch. 03:47

18 A. Not to sound redundant, these are very 03:47  
19 complex issues and each one is separate and 03:47  
20 unique. 03:47

21 Q. And each one needs to be studied in this 03:47  
22 much detail; correct? 03:47

23 A. Absolutely. 03:47

24 Q. Now sitting here off the top of your 03:47  
25 head, without having to dive into these boxes, do 03:47

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1 you know exactly what the blend uniformity issues 03:47

2 were that FDA addressed in 483s regarding Digitek? 03:47

3 A. Without going back and diving into my 03:47

4 boxes, I can't tell you exactly what happened. 03:47

5 Q. Do you know off of top of your head 03:47

6 whether FDA ever cited, warned, sanctioned Actavis 03:47

7 for passing a batch at the blend uniformity stage 03:47

8 that FDA says should have been rejected? 03:47

9 A. There were discussions, if I recall, in 03:48

10 EIRs and 483s with respect to blend uniformity. 03:48

11 Q. That wasn't my question. 03:48

12 A. Okay. What was your question? 03:48

13 MR. MORIARTY: Read it back, Phil, 03:48

14 please. 03:48

15 (Whereupon, the testimony was read 03:48

16 back by the court reporter, as recorded above) 03:48

17 THE WITNESS: I can't off top of my head 03:48

18 answer that question. 03:48

19 BY MR. MORIARTY: 03:48

20 Q. If a pharmaceutical -- let me withdraw 03:48

21 that because I talked with you about that before. 03:49

22 Have you been shown any information whatsoever 03:49

23 to indicate that there was an outbreak of Digoxin 03:49

24 toxicity in 2006, 2007, or 2008 at any hospital, 03:49

25 nursing home, clinic, or outpatient facility in 03:49

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1 the United States? 03:49

2 A. When you say "outbreak" you mean? 03:49

3 Q. Up-tick, increase. 03:49

4 A. I know there's a document in here that 03:49

5 looks at adverse events and the numbers of them, 03:49

6 but that's all -- I would have to look at that and 03:49

7 speak to it. 03:49

8 Q. And you're not a pharmacovigilance 03:49

9 expert? 03:49

10 A. I am not. 03:49

11 Q. And do you know even know whether 03:49

12 adverse event reporting is considered by FDA to be 03:49

13 a causal connection? 03:49

14 A. Causal connection? 03:50

15 Q. Whether adverse event reporting is 03:50

16 necessarily caused by adulterated or out of spec 03:50

17 product? 03:50

18 A. It can be a flag, obviously. 03:50

19 Q. I understand that. 03:50

20 A. Yeah. 03:50

21 Q. For them to look that? 03:50

22 A. Yes. 03:50

23 Q. But if it did, it's not somebody makes 03:50

24 an adverse event report and you automatically 03:50

25 conclude that you have a problem with your 03:50

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1 manufacturing; right? Am I right about that? 03:50

2 A. Say that again, please. And it's late 03:50

3 in the day for me, too, so... 03:50

4 Q. Okay. Let's take a step back. These 03:50

5 lawyers hired a pharmacovigilance expert. 03:50

6 A. Okay. 03:50

7 Q. From Philadelphia, Karen Frank. 03:50

8 A. Okay. 03:50

9 Q. Would you defer to her on these 03:50  
10 pharmacovigilance issues? 03:50

11 A. Yes. 03:50

12 Q. So, what I was trying to -- oh, never 03:51  
13 mind. Other than what you said, about AERs, which 03:51  
14 you would defer to somebody else, you haven't seen 03:51  
15 evidence in medical literature or scientific 03:51  
16 publications that there was some increase in 03:51  
17 Digoxin toxicity in two or three years before this 03:51  
18 recall, have you? 03:51

19 A. I have not specifically gone out and 03:51  
20 looked for that in the literature. 03:51

21 Q. Have you talked to any cardiologists 03:51  
22 about this case, informally or otherwise? 03:51

23 A. In doctor-client privilege, I had 03:51  
24 discussion. 03:51

25 MR. KERENSKY: That's interesting, isn't 03:51

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1 it? 03:51

2 MR. MORIARTY: Yeah, this will be fun. 03:51

3 BY MR. MORIARTY: 03:51

4 Q. Do you take Digoxin? 03:51

5 A. I do not. 03:51

6 Q. And presumably you were not consulting a 03:51

7 doctor about a prescription for yourself -- 03:51

8 A. No. 03:51

9 Q. -- when you were talking about Digoxin; 03:51  
10 correct? 03:51

11 A. That's correct. 03:51

12 Q. And was the party to this conversation 03:52  
13 your primary care physician? 03:52

14 A. Yes. 03:52

15 Q. Is he or she a cardiologist? 03:52

16 A. Yes. 03:52

17 Q. Okay. But the discussion had to do with 03:52  
18 Digitek or Digoxin? 03:52

19 A. Where do we really fall on this? I'm 03:52  
20 not really comfortable talking about what I talked 03:52  
21 about with my doctor regarding this. 03:52

22 Q. Well, if you were talking about your own 03:52  
23 medical care, then it's privileged and I'm going 03:52  
24 somewhere else. If you were talking hey, buddy, 03:52  
25 I'm consulting on this Digitek litigation. What 03:52

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1 do you know about it, what do you think about it, 03:52

2 that's not privileged because you weren't talking 03:52

3 to him about your own medical -- 03:52

4 A. I was not specifically asking him about 03:52

5 that. 03:52

6 MR. KERENSKY: Yeah, we don't 03:52

7 necessarily -- I don't necessary agree with 03:52

8 your characterization of where the line is on 03:53

9 what's privileged. And so there's an argument 03:53

10 just like he made and I made that the line is 03:53

11 here. There's an argument that everything you 03:53

12 talk to your doctor about in your doctor's 03:53

13 office is privileged; okay? I'm sure that's 03:53

14 what the doctor would say under HIPAA. 03:53

15 So it's your call whether or not you want 03:53

16 to share this with him. 03:53

17 THE WITNESS: I prefer not to talk about 03:53

18 it. 03:53

19 MR. KERENSKY: And if you guys want to 03:53

20 press it, just take it up with the Judge; 03:53

21 okay. 03:53

22 BY MR. MORIARTY: 03:53

23 Q. Did you show this doctor any documents 03:53

24 from the Digitek litigation? 03:53

25 A. I didn't think we were going to talk 03:53



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1 about this anymore. 03:53

2 Q. That's a different question. 03:53

3 A. No. 03:53

4 Q. Dr. Bliesner, you are aware that Digitek 03:54  
5 has a theoretical batch yield, are you not? 03:54

6 A. Yes. 03:54

7 Q. So if you put the ingredients in 03:54  
8 appropriately, if you're making .125 Digitek, you 03:54  
9 should get 4.8 million Digitek tablets or 03:54  
10 thereabouts; right? 03:54

11 A. Say that again. 03:54

12 Q. If you put the appropriate ingredients 03:54  
13 into according to the formula, you should get 4.8 03:54  
14 million tablets before waste, sampling, retained 03:54  
15 samples, things of nature? 03:54

16 A. Without having gone back to look at it, 03:54  
17 I'll trust you have the number and that's 03:54  
18 accurate. 03:54

19 Q. Is there always at least some loss or 03:54  
20 waste in the manufacturing process? 03:54

21 A. Invariably, yes. 03:55

22 Q. If a company consistently made 03:55  
23 double-sized tablets, would the actual batch 03:55  
24 production outcomes come close to the theoretical 03:55  
25 yield numbers? 03:55

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1 A. I'm sorry. Say that again. 03:55

2 Q. If the company consistently made 03:55

3 double-sized the tablets -- 03:55

4 A. Uh-huh 03:55

5 Q. -- would the actual batch production 03:55

6 numbers come close to the theoretical yield 03:55

7 numbers? 03:55

8 A. I don't know. I would have to think 03:55

9 about that a little more. I don't think there's a 03:55

10 one-to-one correlation between theoretical yield 03:55

11 and this potential double-thick tablet. I 03:55

12 don't -- I would not speak definitively on that. 03:55

13 I have to really think about it. 03:55

14 Q. Well, if you made an entire batch 03:55

15 somehow of double-thick tablets -- 03:55

16 A. Uh-huh. 03:55

17 Q. -- are you going to get 4.8 million? 03:55

18 A. An entire batch? 03:55

19 Q. Yes, sir. 03:56

20 A. I would say that's probably not going to 03:56

21 get 4.8 million. 03:56

22 Q. If you made one quarter of the tablets 03:56

23 double thick, you wouldn't get close to 4.8 03:56

24 million either, would you? 03:56

25 A. No, I think you have to be very careful 03:56

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1 in trying to make those kinds of assessments 03:56  
2 because we don't know double-thick tablet again 03:56  
3 was ever testified. So we don't know what the 03:56  
4 weight is, we don't know what the total 03:56  
5 excipients, we don't know what the active is. We 03:56  
6 have no idea of being able to just off the top of 03:56  
7 your head, back of envelope calculation say how 03:56  
8 much it would be up short. I just don't think 03:56  
9 it's possible. 03:56

10 Q. Did you ever see any evidence in any 03:56  
11 company documents to indicate that there was some 03:56  
12 adverse trend in Digitek yield production? 03:56

13 A. If I recall, early on there was some 03:57  
14 discussions -- and it may have been with the 03:57  
15 FDA -- with respect to yield difficulties. 03:57

16 Q. What years are you talking about? 03:57

17 A. I don't know. Again, I'd have to go 03:57  
18 back and dig through the documents and look at 03:57  
19 them. 03:57

20 Q. Did any of that occur in 2005, 6, 7 or 03:57  
21 8? 03:57

22 A. I can't tell that you without going back 03:57  
23 and looking through them. 03:57

24 Q. Why, in general, do you think some 03:57  
25 problem that occurred in 1995, for example, is 03:57

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1 evidence that defective Digitek got into the hands 03:57

2 of consumers in 2007 or 2008? 03:57

3 A. It's actually fairly straightforward. 03:57

4 As I said in the report, primary difficulties in 03:57

5 situations like this, in my experience and my 03:57

6 opinion is lack of leadership. It's the number 03:57

7 one. The people who were running the company back 03:58

8 then when they had problems with first consent 03:58

9 decree up until just before the second consent 03:58

10 decree are same people who are running people the 03:58

11 same people on regulatory force, the same people 03:58

12 in quality, the same people that caused all the 03:58

13 initial problems were still there. 03:58

14 Q. Is that some scientific theory? 03:58

15 A. It's a -- it's a statement of fact. 03:58

16 Q. So, in other words essentially what 03:58

17 you're saying is because they were sloppy in '95 03:58

18 means they must have been sloppy in '06 and '07? 03:58

19 A. I think the information that I've 03:58

20 reviewed pretty consistently shows they got out 03:58

21 from underneath the consent decree, they became 03:58

22 recidivistic, and they moved right back into 03:58

23 another situation with many of these same 03:58

24 problems. That reflects on leadership. 03:58

25 Q. But not one thing that you just told me 03:58

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1 is scientific evidence of defective tablets 03:58

2 getting into the hands of consumers. Are you 03:59

3 talking about FDA documents? 03:59

4 A. It's a failure of quality which impacts 03:59

5 the quality of the product going out the door. 03:59

6 Q. Well, if the quality was so bad from '95 03:59

7 through 2008 -- let's just pick that period of 03:59

8 time, those 13 years -- shouldn't there be some 03:59

9 evidence of defective Digitek getting into the 03:59

10 hands of consumers? 03:59

11 A. There are evidence. The pharmacy 03:59

12 individuals. 03:59

13 Q. One tablet out of a billion. Got 03:59

14 anything else? 03:59

15 A. As far as scientific data specifically 03:59

16 showing that it was in the hands of the 03:59

17 individual? 03:59

18 Q. Yes. 03:59

19 A. There was nothing in the record. 03:59

20 However, you know, you have a billion tablets 03:59

21 let's say. It's the number everybody's throwing 03:59

22 around. Start doing the math, say it's .00001 03:59

23 percent, you know, how many tablets is that? 03:59

24 There's a lot of tablets in the market and you may 03:59

25 never seen it. They could hurt the people. 04:00

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1 Q. You may never see it; right? 04:00

2 A. That exists. 04:00

3 Q. Okay. So the one tablet that was found 04:00

4 in 2003 or 4 was found by a pharmacist, wasn't it? 04:00

5 A. I believe that's what we said earlier. 04:00

6 Q. Have you ever worked in a pharmacy? 04:00

7 A. I have not. 04:00

8 Q. Do you have any expertise in pharmacy? 04:00

9 A. A pharmacist? No, sir. 04:00

10 Q. Well, if the one tablet we know about in 04:00

11 2004 could be detected by a pharmacist, isn't it 04:00

12 reasonable to conclude that other extra-thick 04:00

13 tablets, if they existed, would be detected by 04:00

14 pharmacists? 04:00

15 A. Could be. 04:00

16 Q. But that is the only one you know 04:00

17 about. 04:00

18 A. Those two specific instances and the 04:00

19 documents I've reviewed. 04:00

20 Q. Let's talk about sampling rates. Are 04:01

21 you an expert in the design and implementation of 04:01

22 sampling plans for in-process pharmaceutical 04:01

23 testing? 04:01

24 A. I am not. 04:01

25 Q. Do you at least know that in-process 04:01

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1 sampling plans are FDA approved? 04:01

2 A. In the application? Is that what you're 04:01

3 asking? 04:01

4 Q. Initially in the AMDA; correct. 04:01

5 A. I'm not sure whether that specific 04:02

6 sample plan exists in the AMDA. I would have to 04:02

7 take a look. I know procedures, internal guidance 04:02

8 and SOPs companies have with respect to sampling, 04:02

9 and they are pretty unique. 04:02

10 Q. Are you aware of any 483 or warning 04:02

11 letter comment at any point from 2005 to 2008, 04:02

12 which observed problems with Digitek in-process 04:02

13 sampling, meaning weight, thickness? 04:02

14 A. Specific physical testing? 04:02

15 Q. Hardness. 04:02

16 A. I have not seen any that I recall. 04:02

17 Q. And I assume that this sort of 04:02

18 in-process testing in general is supposed to tell 04:02

19 you something about the consistency of the tablets 04:02

20 that are coming off the presses; is that right? 04:02

21 A. At various stages within the process. 04:03

22 It's not like you just grab a hold and spot. 04:03

23 In-process testing involves -- as you said, you've 04:03

24 already said -- blend uniformity at certain steps 04:03

25 along the way. 04:03

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1 Q. Well, right now I'm just talking about 04:03

2 the thickness, hardness, the color, weight. 04:03

3 A. That's kind of -- as far as in-process 04:03

4 goes? 04:03

5 Q. Yeah. 04:03

6 A. I'm not -- okay, I don't recall what 04:03

7 their in-process tests were for this particular 04:03

8 product. 04:03

9 Q. But you've not seen any FDA citations or 04:03

10 warning implicating those processes? 04:03

11 A. Not that I recall. 04:03

12 Q. But I am correct that what you do in 04:03

13 there when QA comes in and the actual press 04:03

14 operator is checking, is to see at least visually 04:03

15 and by measurement whether the tablets are 04:03

16 consistent in size, weight, hardness, things of 04:03

17 that nature; correct? 04:03

18 A. It's a limited testing in process to see 04:03

19 where you are, how it's progressing. 04:04

20 Q. But that's what it's designed to tell 04:04

21 you, limited as it may be? 04:04

22 A. Yes. 04:04

23 Q. So let's talk about finished product 04:04

24 testing, which is within your bailiwick. Did the 04:04

25 AMDA have description of the methods that would be 04:04



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1 used to assay content uniformity and dissolution 04:04

2 tests Digitek at the finished product stage? 04:04

3 A. Not specifically looking at the ANDA. I 04:04

4 remember -- I'm pretty sure the methods would be 04:04

5 in there. They should be. 04:04

6 Q. Are they also -- 04:05

7 A. I need to interject here that I'm not 04:05

8 sure that I had an opportunity to review all of 04:05

9 the sections of the ANDA when they were up on the 04:05

10 website for me. So I got to be careful here. I'm 04:05

11 not sure if I had the whole package 04:05

12 Q. Have you looked at the method operating 04:05

13 instructions or anything else regarding the 04:05

14 testing methods? 04:05

15 A. I have looked at some methods. I would 04:05

16 have to go back and look and see what specific 04:05

17 methods there were. 04:05

18 Q. I didn't see any criticism in your 04:05

19 report of Actavis's method for finished process 04:05

20 testing Digitek. Am I correct about that? 04:05

21 A. There is nothing in the report. 04:05

22 However, I was not pointed specifically to look at 04:05

23 methods in particular. I did not do a wholesale, 04:05

24 soup to nuts -- as I normally do -- review of the 04:05

25 laboratory control system. 04:05

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1 Q. When you say as you normally do in a lab 04:05  
2 control system, you mean for a consulting 04:05  
3 non-litigation project; right? 04:06

4 A. Yes. 04:06

5 Q. Well, certainly if the Plaintiffs' 04:06  
6 lawyers were concerned about the finished product 04:06  
7 methods, they would have probably pointed you in 04:06  
8 that direction; correct? 04:06

9 A. I wouldn't make that conclusion. We ran 04:06  
10 out of time as much as anything else. 04:06

11 Q. And excuse me if I asked you this 04:06  
12 before, but you have not seen in any 483 or 04:06  
13 warning letter any sort of statement by FDA that 04:06  
14 Actavis's finished product testing of Digitek was 04:06  
15 in some way deficient; correct? 04:06

16 A. No, we did not talk about that. And I 04:06  
17 vaguely recall that there are discussions with 04:06  
18 respect to analytical methods not being sufficient 04:06  
19 for their intended use and/or validated in some of 04:06  
20 these documents that the FDA has generated. I 04:06  
21 have to go back and look at them. 04:07

22 Q. For Digitek? 04:07

23 A. I can't say for certain, but I know that 04:07  
24 there are discussions through 483s and warnings 04:07  
25 letters with respect to the laboratory records and 04:07

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1 methods. 04:07

2 Q. Did FDA ever say that there was a batch 04:07

3 that had out-of-spec results that should have been 04:07

4 rejected because the methods or even the 04:07

5 investigations were inadequate? 04:07

6 A. Methods? 04:07

7 Q. Or investigations? 04:07

8 A. Or investigations. Again, I'd have to 04:07

9 go back and look at it because there are 04:07

10 discussions with respect to methods, methods 04:07

11 validation and testing that come up throughout 04:07

12 these FDA documents. 04:07

13 Q. But my question is very specific. 04:07

14 A. Okay. 04:08

15 Q. Do you remember any statements in any 04:08

16 FDA documents to the effect that Digitek batches 04:08

17 should have been rejected because analytical 04:08

18 methods were inadequate or investigations were 04:08

19 inadequate? 04:08

20 A. I can't say that off the top of my 04:08

21 head. I really can't. Analytical methodology is 04:08

22 invariably one of the observations the FDA makes 04:08

23 for companies in trouble. 04:08

24 Q. Let's go to page 7 of your report. 04:08

25 MR. KERENSKY: Can we take a stretch 04:09

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1 break after you finish this thing, this little 04:09

2 subject? 04:10

3 MR. MORIARTY: How long on the tape? 04:10

4 THE VIDEOGRAPHER: 25 minutes. 04:10

5 MR. MORIARTY: Yeah. 04:10

6 BY MR. MORIARTY: 04:10

7 Q. Okay. Page 7. 04:10

8 A. Yes. 04:10

9 Q. It says product recalls. 04:10

10 A. Yes. 04:10

11 Q. The first one is in 1990. Was that 04:10

12 Digitek? 04:10

13 A. I don't know. 04:10

14 Q. What would you have to look at to figure 04:10

15 it out? 04:10

16 A. It was just a -- if I recall, it was a 04:10

17 business summary that was presented by one of the 04:10

18 CEOs and it just said there was a product recall. 04:10

19 If I -- I'm pulling this off my memory, which I 04:10

20 hesitate to do that. 04:10

21 Q. In 1995, Class III? 04:10

22 A. Uh-huh. 04:10

23 Q. That's not recalled at the consumer 04:10

24 level; correct? 04:10

25 A. Uh-huh. 04:10

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1 Q. Is that right? 04:10

2 A. That's correct. 04:10

3 Q. Because of incorrect package insert. 04:10

4 Which is, in your words, a failure of packaging 04:11

5 and labeling portions of the cGMPs; correct? 04:11

6 A. Correct. 04:11

7 Q. Was it Digitek? 04:11

8 A. I'd have to look. That may be one of 04:11

9 those things as well that was just stated as. 04:11

10 Q. And certainly FDA or Amide at the time 04:11

11 didn't consider this as a patient safety issue 04:11

12 because it was a Class III recall; correct? 04:11

13 A. Correct. An immediate threat. 04:11

14 Q. And the 2008 August total product 04:11

15 recall, which is the last one that you list -- 04:11

16 A. Yes. 04:11

17 Q. -- that was a Class III recall, wasn't 04:11

18 it? 04:11

19 A. I don't recall. 04:11

20 Q. Well, that's important to know, isn't 04:11

21 it? 04:11

22 A. Let's take a look. 04:11

23 MR. MORIARTY: Let me make sure we're on 04:12

24 the same page. 04:12

25 THE WITNESS: Okay. 04:12

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1 BY MR. MORIARTY: 04:12

2 Q. Was the 2008 August recall to the 04:12

3 consumer level? 04:12

4 A. What page were we on again back in the 04:12

5 document? 04:12

6 Q. Seven. 04:12

7 A. Seven? 04:12

8 Q. But you don't have a reference? 04:12

9 A. Seven, the August recall? 04:12

10 Q. Yeah, I guess you would be looking at 04:12

11 A49, A55, 63. That's what your table says 04:12

12 A. 25 April, 2008? 04:13

13 Q. No, sir. August 2008. It would be your 04:13

14 reference A63. 04:13

15 A. 63. 04:13

16 Q. And on page 61 of your report you say 04:13

17 that it was recalled at the retail level. 04:13

18 A. Where in the report? 04:13

19 Q. Page 61. 04:13

20 A. Yeah. 61, reference A63? 04:13

21 Q. Yes, sir. 04:14

22 A. Recall from press release, FDA website 04:14

23 "Actavis auto announces voluntary recall at retail 04:14

24 level of all drugs manufactured." Then that's 04:14

25 what that was. 04:14

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1 Q. All right. So even though FDA may have 04:14  
2 been concerned about good manufacturing practice 04:14  
3 violations in 2008 or 2007, there was not a recall 04:14  
4 of these other products to the consumer level; 04:14  
5 correct? 04:14

6 A. According to that. 04:14

7 MR. MORIARTY: Okay. You want to take a 04:14  
8 stretch break? Let's go off the record for -- 04:14

9 MR. KERENSKY: Thank you for remembering. 04:15

10 MR. MORIARTY: For five minutes. 04:15

11 THE VIDEOGRAPHER: The time is 4:17 p.m. 04:15  
12 We're going off the record. 04:15

13 THE VIDEOGRAPHER: The time is now 04:25  
14 4:28 p.m. We are back on the record. 04:25

15 (Whereupon, Exhibit 106 was marked 04:26  
16 for identification) 04:26

17 BY MR. MORIARTY: 04:26

18 Q. Okay. I'm going to show you what has 04:26  
19 been marked as Exhibit 106; okay? This is a 04:26  
20 notice of your deposition for today; all right? 04:26

21 A. Okay. 04:26

22 Q. Have you seen that before? 04:26

23 A. I have. 04:26

24 Q. All right. And it tells you to bring a 04:26  
25 lot of stuff; right? 04:26

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1 A. Yes. 04:26

2 Q. So when this is going to be restarted on 04:26

3 the 18th, there will be a new notice that goes 04:26

4 out. You will have to bring your stuff and 04:26

5 somehow the lawyers will figure out a way to get 04:26

6 this hard drive duplicated so we can find these 04:26

7 other things; okay? 04:26

8 A. Okay. 04:26

9 Q. So it's possible you'll have to be in 04:26

10 communication with people between now and then -- 04:26

11 A. Yes. 04:26

12 Q. -- to facilitate that; all right. 04:26

13 Okay. Fair enough. 04:27

14 MR. ANDERTON: We should plan to start 04:27

15 perhaps as early at 8 o'clock on the 18th? 04:27

16 THE WITNESS: That's fine. 04:27

17 BY MR. MORIARTY: 04:27

18 Q. Let's go to page 8 of your report. Do 04:27

19 you see in the middle of the page where you have 04:27

20 the three bullet points? 04:27

21 A. Yes. 04:27

22 Q. Does it gives the three addresses? 04:27

23 A. Yes. 04:27

24 Q. All right. Do you know that Taft Road 04:27

25 was only a packaging facility for Digitek? 04:27



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1 A. I knew that it was in limited 04:27  
2 operations. Specifically packaging, I don't know 04:27  
3 if I could -- I could say that definitively 04:27  
4 without going back and looking at the EIR. 04:27

5 Q. Do you remember anything in a 483 or a 04:27  
6 warning letter or an EIR to the effect that there 04:28  
7 was a problem in any facility of Taft Road that 04:28  
8 affected the potency of Digitek that made it to 04:28  
9 consumers? 04:28

10 A. I can't say without going back. It gets 04:28  
11 pretty complex on what the facilities are and how 04:28  
12 they are, what's going on at them. It's kind of a 04:28  
13 mess just breaking out what the three were. So 04:28  
14 I -- I can't definitively answer that, sorry. 04:28

15 Q. And do you know what was going on at 990 04:28  
16 Riverview Drive? 04:28

17 A. Again, it's the same thing. Very 04:28  
18 confusing reviewing documents what specific 04:28  
19 operations were going on at these individual 04:28  
20 facilities. 04:28

21 Q. Well -- 04:28

22 A. And how they impacted or didn't. 04:28

23 Q. Hypothetically I want to you assume that 04:28  
24 all that was going on at Riverview was -- from a 04:29  
25 production standpoint was the attempt to validate, 04:29

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1 process validate a new location with different 04:29  
2 equipment to manufacture Digitek; okay? 04:29  
3 A. Theoretically; okay. 04:29  
4 Q. No. 04:29  
5 A. That's what you're saying. 04:29  
6 Q. No, I'm asking you to assume that. 04:29  
7 A. Hypothetically. 04:29  
8 Q. And that no product from Riverview was 04:29  
9 ever released to market at all; okay. 04:29  
10 A. If that's what you say hypothetically, 04:29  
11 yeah. 04:29  
12 Q. So if, for example, they had a problem 04:29  
13 some day with an oil leak on a tableting machine 04:29  
14 and tablets got oily but were, you know, rejected 04:29  
15 because they were not going to market anyway, that 04:29  
16 wouldn't affect the potency of Digitek that 04:29  
17 actually was made at Little Falls and shipped to 04:29  
18 consumers, would it? 04:30  
19 A. What facility are we talking about? 04:30  
20 Q. Riverview. 04:30  
21 A. Riverview. Okay. And you're saying 04:30  
22 that hypothetically if there was problem at 04:30  
23 Riverview where they're only doing process 04:30  
24 validation; is that correct? 04:30  
25 Q. Yeah. 04:30

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1 A. That that action would not influence 04:30

2 what was going on at the Little Falls facility. 04:30

3 Is that what you're saying? 04:30

4 Q. Yes. 04:30

5 A. Yes, hypothetically, yes. 04:30

6 Q. Okay. Well, do you have any evidence 04:30

7 that any Digitek that was made at Riverview was 04:30

8 released to consumers? 04:30

9 A. Other than going back and digging 04:30

10 through documents, I can't say that explicitly. 04:30

11 I -- it's just -- it's too much to go back and 04:30

12 piece together. 04:30

13 Q. Okay. Miss Donahue represents Mylan. 04:31

14 Do you know who Mylan is? 04:31

15 A. I do. 04:31

16 Q. Do you know that they were only a 04:31

17 distributor not a manufacturer of Digitek? 04:31

18 A. Is that a totally accurate statement 04:31

19 because I don't know if I understand the 04:31

20 relationship, UDL, Bertek, how they fall into 04:31

21 that. 04:31

22 Q. Do you know whether Digitek was ever 04:31

23 manufactured by anyone other than Amide or 04:31

24 Actavis? 04:31

25 A. I don't know that definitively because I 04:31

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1 know there was discussion that Mylan was going to 04:31

2 take it over via UDL or Bertek, so I don't know. 04:31

3 Q. Well, have you seen any documents to 04:31

4 indicate that Mylan or UDL ever manufactured 04:31

5 tablets of Digitek? 04:32

6 A. I don't believe that they did. 04:32

7 MR. MORIARTY: Okay. The bottom line is 04:32

8 she has a couple of questions that she wants 04:32

9 to get out of the way during session one. So 04:32

10 I'm going to let her ask those questions and 04:32

11 then if there's time left on my tape, I'll get 04:32

12 back to you; okay? 04:32

13 THE WITNESS: Okay. 04:32

14 DIRECT EXAMINATION 04:32

15 BY MS. DONAHUE: 04:32

16 Q. Good afternoon, Dr. Bliesner. 04:32

17 A. Hello. 04:32

18 Q. I have reviewed your -- first, let me 04:32

19 start by asking you this. 04:32

20 A. Yes. 04:32

21 Q. You are not an expert in pharmaceutical 04:32

22 distribution, are you? 04:33

23 A. Distribution, no. 04:33

24 Q. And you're not an expert on the industry 04:33

25 practices related to pharmaceutical distribution? 04:33

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1 A. Distribution, no. 04:33

2 Q. You're not expert on the FDA regulations 04:33

3 applicable to pharmaceutical distribution? 04:33

4 A. I have not -- I mean don't even know 04:33

5 what specifically the regulations would relate to 04:33

6 distribution, so, no. 04:33

7 Q. So you're not expert? 04:33

8 A. No. 04:33

9 Q. And you've never published any articles, 04:33

10 textbooks, treatises on pharmaceutical 04:33

11 distribution practices? 04:33

12 A. I have not. 04:33

13 Q. Now, I reviewed your 21-plus attachment 04:33

14 page report before coming here today. 04:33

15 A. Yes. 04:33

16 Q. And the purpose of that report is set 04:33

17 forth on page 1 of your report; correct? 04:33

18 A. Correct. 04:33

19 Q. And can you read that purpose out loud, 04:33

20 please, for the record? 04:34

21 A. Sure. Purpose: "This report is a 04:34

22 thorough, detailed, independent review of the 04:34

23 facts related to Digitek product litigation. In 04:34

24 particular, this review is specifically conducted 04:34

25 to determine if Amide Pharmaceutical, Inc. which 04:34

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1 later became Actavis Totowa, LLC and referred to 04:34  
2 as Amide/Actavis within this report, demonstrated 04:34  
3 a systematic failure to implement quality systems 04:34  
4 which in turn created a high likelihood that 04:34  
5 adulterated product made it to the marketplace." 04:34

6 Q. Thank you. And is that an accurate 04:34  
7 statement of the purpose of your report? 04:34

8 A. Yes. 04:34

9 Q. And I think you told me -- you told us 04:34  
10 earlier in response to Mr. Moriarty's questions, 04:34  
11 that -- let's see. When you first were contacted 04:34  
12 by Plaintiffs' counsel in these cases, your task 04:34  
13 or the guidance they gave you was to evaluate the 04:34  
14 status of Actavis's or Amide's compliance with 04:34  
15 GMPs; is that correct? 04:34

16 A. Yes, that's correct. 04:34

17 Q. If we turn to page -- the bottom of page 04:35  
18 20 of your report under the heading root causes 04:35  
19 for Amide Pharmaceutical and Actavis's failure to 04:35  
20 comply with GMPs which led to release of 04:35  
21 adulterated product to market. 04:35

22 A. Yes. 04:35

23 Q. You see that there? 04:35

24 A. I do. 04:35

25 Q. And then you have list of the root 04:35

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1 causes; right? 04:35

2 A. Yes. 04:35

3 Q. And nowhere among the one, two, three, 04:35

4 four, five root causes that you've identified in 04:35

5 your report is there mention of any conduct on 04:35

6 behalf of -- or on the part of Mylan or UDL as a 04:35

7 root cause; is that correct? 04:35

8 A. Specifically, "yes, but." Mylan was 04:36

9 contracted to have amide then or Actavis 04:36

10 manufacture the tablets, and there was no quality 04:36

11 agreement that was in place that I saw in the 04:36

12 record. 04:36

13 So lack of quality assurance oversight 04:36

14 overlaps into that because the innovator, as I 04:36

15 understand, or the head of the contract -- Mylan 04:36

16 in this case as I understand as I read it -- is 04:36

17 responsible for the product as well and making 04:36

18 sure that their contractors, contract 04:36

19 manufacturers, whatever, follow the GMPs. 04:36

20 Q. Have you been asked in this case by 04:36

21 Plaintiffs' counsel to provide an opinion as to 04:36

22 Mylan's alleged liability? 04:36

23 A. Formally, prior to this? 04:36

24 Q. Yes. 04:36

25 A. Prior to this session? 04:37

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1 Q. Yes. 04:37

2 A. No. 04:37

3 Q. Prior to authoring your report, were you 04:37

4 asked by Plaintiffs' counsel to render a report as 04:37

5 to Mylan's liability in these cases? 04:37

6 A. I recall the discussion with the Miller 04:37

7 law firm regarding Mylan and asked for guidance. 04:37

8 This is from memory, so it's not written down. 04:37

9 It's a bit vague. And they -- their guidance was, 04:37

10 you know, however they fit into this, put it in 04:37

11 your report as you see fit. 04:37

12 Q. And you saw fit not to mention Mylan 04:37

13 specifically or any specific Mylan conduct in the 04:37

14 report that you've stated was -- was written for 04:37

15 the purpose of advising counsel as to what your 04:37

16 opinions are in this case. 04:37

17 A. There are references in the attachment 04:37

18 section to discussions with Mylan that talk about 04:38

19 quality issues they were concerned with for some 04:38

20 time. 04:38

21 Q. Okay. Can you please point to me -- 04:38

22 A. Sure. 04:38

23 Q. -- in your attachments every reference 04:38

24 to Mylan. 04:38

25 A. Okay. 04:38



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1 MR. MORIARTY: I think this is going to 04:38

2 take a couple of minutes. You might want to 04:38

3 go off the video record. 04:38

4 THE VIDEOGRAPHER: The time is 4:41 p.m. 04:38

5 We're going off the record briefly. 04:38

6 (Short break) 04:39

7 THE VIDEOGRAPHER: The time is now 04:39

8 4:49 p.m. We are back on the record. 04:46

9 BY MS. DONAHUE: 04:46

10 Q. All right. Dr. Bliesner, off the record 04:46

11 you were reviewing your report -- 04:46

12 A. Yes. 04:46

13 Q. -- in order to answer my question which 04:46

14 was where -- will you please point out every 04:46

15 reference in your report to a Mylan document. 04:46

16 A. Yes. The other question I have, are you 04:46

17 considering UDL Bertek to be part of the Mylan 04:47

18 umbrella? 04:47

19 Q. Sure. 04:47

20 A. Okay. Page 15, number 33. 04:47

21 Q. Uh-huh. Yes. Thank you. We have 04:47

22 number page 15, number 33? 04:47

23 A. Yes. 04:47

24 Q. Yes. 04:47

25 A. Page 18, number 46. 04:47

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1 Q. Yes. 04:47

2 A. And number 49. Page 19, number 54. 04:47

3 Q. Any others? 04:47

4 A. Yes. Page 41, number A24; page 43, A28; 04:47

5 page 46, A33; page 47, A36; page 54, A44; page 56 04:48

6 A 49; page 57 A52; page 58, A53. 04:49

7 There is a reference to Bertek UDL in A55 on 04:50

8 page 59, embedded in the press release, and on 04:50

9 page 60, A59. And I believe with that quick 04:50

10 review of the report, that should be most all of 04:50

11 them. 04:50

12 Q. Thank you. 04:50

13 A. Uh-huh. 04:50

14 Q. Now each of those references that you've 04:50

15 just given us to Mylan documents, are just that; 04:50

16 correct? They are references to Mylan documents 04:50

17 and in some instances quotations from the 04:50

18 documents; is that correct? 04:50

19 A. For e-mails, yes. 04:50

20 Q. And nowhere in the course of those 04:50

21 references have you rendered an opinion in regard 04:50

22 to Mylan or UDL's conduct in distributing Digitek? 04:50

23 A. In this report? 04:51

24 Q. Yes. 04:51

25 A. I have not written it in the report. I 04:51

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1 do have an opinion, but I have not written it in 04:51  
2 the report. 04:51

3 Q. Did you have an understanding as you 04:51  
4 came here today that your report was to contain 04:51  
5 the totality of your opinions that you intend to 04:51  
6 render at trial in this case? 04:51

7 A. With respect to the guidance that I got, 04:51  
8 thought and think and do believe that I put the 04:51  
9 information that was desired specifically related 04:51  
10 to Digitek, Actavis Totowa. That was my guidance. 04:51

11 MR. MORIARTY: You have 60 seconds. 04:51

12 BY MS. DONAHUE: 04:51

13 Q. As you sit here today, what is your 04:52  
14 opinion with regard to Mylan's conduct in the 04:52  
15 distributing Digitek in the case, Mylan and UDL? 04:52

16 A. Just based upon the documents that I 04:52  
17 reviewed and, again, not concentrating on Mylan's 04:52  
18 position in this thing, I found it odd and not 04:52  
19 customary that no quality agreement was in place. 04:52

20 Q. You would agree, would you not, that 04:52  
21 quality agreements are not required by the FDA 04:52  
22 regulations? 04:52

23 A. By regulations? Specifically in 21 CFR 04:52  
24 210 and 211, not to my knowledge is there a 04:52  
25 requirement for a quality agreement. It is 04:52

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1 standard industry practice. 04:52

2 Q. That's a relatively new standard 04:52

3 industry practice, would you agree with that? 04:52

4 A. Relatively new? I'm not sure how you 04:52

5 define relatively new. 04:52

6 Q. In your opinion, when did it become 04:53

7 standard industry practice? 04:53

8 A. Well, let's see. For the last -- at 04:53

9 least the last three to five years in my 04:53

10 consulting endeavors I've expected and seen 04:53

11 quality agreement with contractors. 04:53

12 Q. Do you understand that as you sit here 04:53

13 today, Dr. Bliesner, that Mylan or -- neither 04:53

14 Mylan or UDL was the innovator in regard to 04:53

15 Digitek? In other words, neither one of them held 04:53

16 the ANDA? 04:53

17 A. That is correct. I understand that. 04:53

18 MS. DONAHUE: Since we're almost out of 04:53

19 tape, I'm going to stop questioning now, but I 04:53

20 reserve the right to come back. 04:53

21 Oh, yeah. Before we go off the record, 04:53

22 let me finish my sentence. I reserve the 04:53

23 right to come back and continue my 04:53

24 questioning. And you've been, I think, taking 04:53

25 some notes during the deposition and we would 04:53

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1 like to get those marked as an exhibit, 04:54

2 please. 04:54

3 THE WITNESS: Okay. 04:54

4 MS. DONAHUE: Let's wait. Before we go 04:54

5 off the record, let's mark them. 04:54

6 MR. KERENSKY: You didn't write anything 04:54

7 down about Mr. Anderton's tie, did you? 04:54

8 THE WITNESS: No, it was noted though. 04:54

9 MR. KERENSKY: Okay. 04:54

10 MR. ANDERTON: I will accept the 04:54

11 compliment. 04:54

12 (Whereupon, Exhibit 109 was marked 04:54

13 for identification) 04:54

14 THE VIDEOGRAPHER: The time is now 04:54

15 4:57 p.m. We're going off the record. 04:54

16

17 (THEREUPON, the taking of the deposition  
18 was concluded at 4:57 p.m.)

19

20

21

22

23

24

25

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1 CERTIFICATE OF OATH

2

3 STATE OF FLORIDA

4 COUNTY OF HILLSBOROUGH

5

6 I, the undersigned authority,  
7 certify that David Bliesner, Ph.D., personally  
8 appeared before me and was duly sworn by me.

9 WITNESS my hand and official  
10 seal, this 3rd day of February, 2011.

11

12

13

14 \_\_\_\_\_  
15 PHILIP RYAN, RPR  
16 NOTARY PUBLIC - STATE OF FLORIDA  
17 COMMISSION # DD 988415  
18 MY COMMISSION EXPIRES: JUNE 28, 2014

19

20

21

22

23

24

25

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1 CERTIFICATE OF REPORTER

2 STATE OF FLORIDA

3 COUNTY OF HILLSBOROUGH

4 I, PHILIP RYAN, RPR, certify that I  
5 was authorized to and did stenographically  
6 report the foregoing deposition; and that the  
7 foregoing transcript is a true record of the  
8 testimony given by the witness.

9 I further certify that I am not a  
10 relative, employee, attorney, or counsel of any  
11 of the parties, nor am I a relative or employee  
12 of any of the parties' attorneys or counsel  
13 connected with the action, nor am I financially  
14 interested in the action.

15

16 DATED this 3rd day of February,  
17 2011.

18

19

20

21

22 \_\_\_\_\_  
PHILIP RYAN, RPR

23

24

25

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